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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,172	11/20/2000	Hideaki Suzuki	2167-0116P	6879

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EXAMINER	
DO, PENSEE T	14

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,172	SUZUKI ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-19* is/are pending in the application.

4a) Of the above claim(s) *11-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-9* is/are rejected.

7)☒ Claim(s) *6 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

The request for continued examination under 37 CFR 1.114 filed on December 17, 2002 has been acknowledged and entered as paper no. 14.

Amendment Entry & Claim Status

The amendments filed on August 12, 2002 and December 19, 2002 have been acknowledged and entered. Claims 1-9, 11-19 are pending. Claims 11-18 are withdrawn from consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 fails to further limit claim 1 because claim 8 recites a broader limitation, i.e. an anti-human medallusin antibody instead of the anti-human medallusin *monoclonal* antibody as recited in claim 1.

Claim 9 fails to further limit claim 1 because its limitation is basically the same as that of claim 8.

Claim 10 fails to further limit claim 8, which depends from claim 1, because it limits the anti-human medallusin antibodies used in claim 1 to be monoclonal which has been a limitation of claim 1 already.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki et al. (Clinica Chimica ACTA (Dec 15 1988) 178(2) 193-204) in view of Voet et al. (Biochemistry 1990) and Aoki et al. (JP 11151085A) (*Aoki-JP*).

Aoki teaches an enzyme immunoassay of medullasin in peripheral blood. Medullasin is located in granulocytes (leukocytes) and bone marrow cells. The medullasin protein is extracted and purified for antibody generation in rabbits. A solid support is coated with an anti-medullasin IgG antibody. The coated bead is incubated with an amount of diluted peripheral blood to bind the medullasin. After incubation, the complex is incubated with an enzyme labeled conjugate and the amount of activity of the label is determined (pages 195-196).

However, Aoki does not teach using an aqueous liquid for lysing cells. Voet teaches isolation of protein located in cytosol of cells by osmolysis. Isolation of protein requires that the protein is in solution. Therefore, cells are suspended in a hypotonic solution and under the influence of osmotic forces, water diffuses into the more

concentrated intracellular solution thereby causing the cells to swell and burst thus releasing the protein of interest (page 76).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Aoki by suspending cells comprising the protein of interest into a buffer solution having an osmotic pressure sufficient to allow osmolysis of the cell as taught in the method of Voet because Voet teaches that osmolysis of cells for protein isolation is conventional in the art and is efficient, simplest, and gentlest method known.

Both Aoki and Voet fail to teach the use of an anti-human medullasin monoclonal antibody.

Aoki-JP teaches an anti-human medullasin monoclonal antibody which is used for identifying the human medullasin existing in granulocytes. In operation, the labeled antibody is fixed in an insoluble carrier. The sample containing the human medullasin is contacted with the carrier, when the human medullasin is caught on the carrier, the labeled complex is then assayed. (see abstract).

It would have been obvious to one of ordinary skills in the art to use the anti-human medullasin monoclonal antibody as taught by Aoki-JP in the combined method of Aoki and Voet because monoclonal antibodies are known for their binding specificity.

Claims 2-5, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Aoki in view of Voet and Aoki-JP as applied to claims 1, 8-10 above and further in view of Lapicola (US 4,745,071).

See discussion on Aoki and Voet set forth above. These references differ from the invention in failing to teach a specific buffer or lysing agent for cells. Lapicola teaches a method for the volumeric differentiation of blood cell types. The reagents used comprise a diluent with an osmolality that can be adjusted to 320 +/-5 milliosmoles with sodium chloride. The level of the diluent can be set at a level other than 320 +/- 5 milliosmoles. The organic buffers comprise various acids and alcohols (col. 5, lines 35-55). A surfactant such as quaternary ammonium salts comprising three alkyl short chain groups may be added to the diluent as a lysing agent. The studies of the quaternary ammonium salts in blood show lysing of various leukocyte populations (col. 6, lines 32-68).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate in the modified method of Aoki the buffers comprising lysing reagent as taught in the method of Lapicola because Lapicola teaches that quaternary salts disclosed in the diluent buffers were capable of lysing leukocyte populations in blood. Therefore, one would have been motivated to incorporate a solution comprising a surfactant such as a quaternary salt for lysing of leukocytes for the quantification of medullasin activity in a blood sample.

Response to Arguments

Applicant's arguments filed on August 12, 2002 have been fully considered but they are not persuasive.

Applicants narrow the claims to read "anti-human medallusin monoclonal antibody" and submit that the present invention differs from the prior art that it uses a

monoclonal antibody. By contrast, Aoki measure the medullasin by a polyclonal antibody.

This argument is moot in view of the newly applied reference Aoki-JP in the rejection.

Conclusion

Claims 6 and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641
3/5/03

Pensee T. Do
Patent Examiner
March 6, 2003